

## COMPTROLLER GENERAL OF THE UNITED STATES WASHINGTON, D.C. 20548

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B-164031(5)

MAY 1, 1979

The Honorable Bob Eckhardt
Chairman, Subcommittee on Oversight
and Investigations
House Committee on Interstate and
Foreign Commerce

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√The Honorable Jack Brooks
Chairman, House Committee on Government
Operations

HSE 01500

The Honorable George E. Danielson
Chairman, Subcommittee on Administrative
Law and Governmental Relations
House Committee on the Judiciary

1196 02501

The Honorable John D. Dingell
Chairman, Subcommittee on Energy
and Power
House Committee on Interstate and
and Foreign Commerce

HSE02303

The Honorable Henry A. Waxman Chairman, Subcommittee on Health and the Environment House Committee on Interstate

11SE 02304

The Honorable Walter Flowers House of Representatives

and Foreign Commerce

On September 19, 1978, we reported to you that the Department of Health, Education, and Welfare (HEW) had adequately audited the swine flu vaccine manufacturing costs claimed by three manufacturers—Merrell—National Laborator—ies; Merck, Sharp, and Dohme; and Wyeth Laboratories. We also reported that, despite the lack of a final contract, HEW had begun its audit of the costs claimed by the fourth manufacturer—Parke, Davis, and Company—and that we were monitoring the audit. HEW has completed audit work at Parke—Davis, and we are reporting to you now on its adequacy.

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In our opinion, the work performed by HEW was adequate and should give the contracting officer a reasonable basis for negotiating the contract costs. During our review we noted that HEW had encountered a problem in determining how to evaluate the reasonableness of over \$200,000 of claimed general and administrative expenses. We proposed that HEW consider using the cost of goods sold as a basis for evaluation. Using our proposed method, the HEW auditors determined that the claimed costs were acceptable instead of classifying them as unresolved.

HEW's audit of Parke-Davis included only costs associated with the production of A/Victoria/3/75 or A/New Jersey/76 (swine) flu vaccines—about \$13.5 million. Parke-Davis also included in its cost claim about \$1.4 million for producing a Shope strain vaccine which is closely related to the A/New Jersey/76 vaccine and which was mistakenly produced for the swine flu program. HEW's contracting officer determined that these costs are ineligible for reimbursement because the vaccine failed to meet contract specifications. Parke-Davis has appealed the contracting officer's decision to the Armed Services Board of Contract Appeals. As a result, Shope vaccine costs were not subject to audit.

Parke-Davis has now signed a final contract, but the Shope vaccine dispute remains unresolved. Because (1) the timing of resolution of this dispute is uncertain and (2) HEW has completed acceptable audit work for all but the Shope vaccine costs, unless you request further work, this report will complete the work requested.

HEW's contracting officer told us that final negotiations have begun with Merrell-National Laboratories and should begin soon with Merck, Sharp, and Dohme and Wyeth Laboratories. He said the negotiation process could take several months for each manufacturer, because the HEW auditors recommended major cost disallowances on each contract.

If you desire, we would be pleased to discuss the details of the above matters with you or your staff.

As arranged with your offices, we are sending copies of this report to the Secretary of Health, Education, and Welfare; the Director, Office of Management and Budget; and the Director, Center for Disease Control. Copies will also be available to other parties who request them.

Comptroller General of the United States